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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,121	06/01/2007	Jakob Felding	205170205421-US0	4503
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DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER ANDERSON, JAMES D	
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			1614	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/599,121

**Applicant(s)**

FELDING ET AL.

**Examiner**

JAMES D. ANDERSON

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 11, 21, 23-29 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8, 11, 21, 23-29 and 31-37 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 11, 21, and 23-29, drawn to methods of treating cancer comprising administering a compound of Formula I, IIa, IIb, IIc, or IId, wherein V1, V2, V3, and V4 form a benzene ring.

Group II, claim(s) 1-8 and 24-29, drawn to methods of treating cancer comprising administering a compound of Formula I, IIa, IIb, IIc, or IId, wherein V1, V2, V3, and V4 form a pyridine ring.

Group III, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a thiophene ring.

Group IV, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a furan ring.

Group V, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a pyrazole ring.

Group VI, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form an imidazole ring.

Group VII, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a pyrimidine ring.

Group VIII, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a pyrazine ring.

Group IX, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a pyridazine ring.

Group X, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a thiazole ring.

Group XI, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a isothiazole ring.

Group XII, claim(s) 1-2, 4-8, and 28-29, drawn to methods of treating cancer comprising administering a compound of Formula I wherein V1, V2, V3, and V4 form a thiophene ring.

Group XIII, claim(s) 31-32 and 34-37, drawn to compounds of Formula I or II, wherein V1, V2, V3, and V4 form a benzene ring.

Group XIV, claim(s) 31-32 and 34-37, drawn to compounds of Formula I or II, wherein V1, V2, V3, and V4 form a pyridine ring.

Group XV, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a benzene ring.

Group XVI, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a pyridine ring.

Group XVII, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a thiophene ring.

Group XVIII, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a furan ring.

Group XIX, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a pyrazole ring.

Group XX, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a imidazole ring.

Group XXI, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a pyrimidine ring.

Group XXII, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a pyrazine ring.

Group XXIII, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a pyridazine ring.

Group XXIV, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a thiazole ring.

Group XXV, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form an isothiazole ring.

Group XXVI, claim(s) 33, drawn to a pharmaceutical composition comprising a compound as defined in claim 1, wherein V1, V2, V3, and V4 form a thiophene ring.

The inventions listed as Groups I-XXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the compounds of Formula I as defined in claim 1 encompass distinct compounds with no common structural feature linking the claimed compounds. The definitions of the V1, V2, V3, and V4 substituents define structurally distinct compounds (e.g., compounds having benzene rings, thiophene rings, pyrimidine rings, pyridine rings, pyrazine rings, etc.). Further, WO 03/078394 and WO 99/26611 define compounds which correspond to compounds of Formula I recited in the instant claims wherein V1, V2, V3, and V4 form a benzene ring. As such, the claimed compounds having a benzene ring were known in the art and thus are not a special technical feature linking Groups I-XXVI. Also see Natarajan et al. (J. Med. Chem., March 2004, vol. 47, pages 1882-1885) which teaches compounds of Formula I as recited in the instant claims wherein V1, V2, V3, and V4 form a benzene ring.

#### ***Election of Species Requirement for Groups I-XXVI***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The multitude of compounds encompassed by Applicant's definitions of  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^N$ ,  $>Y(=Q)_n$ ,  $X^1$ , and  $X^2$ .

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. **To be responsive to this requirement, Applicant is required to identify a specific compound by name and/or structure and to specifically identify the  $V^1$ ,  $V^2$ ,  $V^3$ ,  $V^4$ ,  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^N$ ,  $>Y(=Q)_n$ ,  $X^1$ , and  $X^2$  substituents (e.g., a compound of Formula I wherein V1, V2, V3, and V4 are C; R1 is**

**methyl; R2 is chloro; R3 and R4 are hydrogen; RN is hydrogen;  $>Y(=Q)n$  is  $C=O$  wherein n is 1; X1 is hydroxy; and X2 is methyl, i.e., compound 59 as defined at page 47 of the specification).** The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-8, 11, 21, 23-29, and 31-37 correspond to species of compounds of Formula I.

The following claim(s) are generic: 1-8, 11, 21, 23-27, 29, and 31-37.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: compounds of Formula I wherein V1, V2, V3, and V4 form a benzene ring are known in the art as discussed supra. As such, Applicant's definitions of  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^4$ ,  $R^N$ ,  $>Y(=Q)_n$ ,  $X^1$ , and  $X^2$  do not define compounds having a special technical feature over the prior art compounds.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

***Notice of Possible Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Joint Inventors***

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/  
Examiner, Art Unit 1614